Crystal Creek™
the natural choice for agriculture

August 12, 2005

Mr. Arthur Neal
Director, Program Administration, NOP/USDA-AMS-TMP
Room 4008 – So. Ag Stop 0268
1400 Independence Ave., SW
Washington, DC, 20250

RE: Docket # Tm-04-07, NOP, Sunset Review.

Dear Mr. Neal:

As owner and president of Crystal Creek, Inc., a company that is dedicated to supporting the organic livestock industry with nutritional and herd health management consulting, I appreciate the opportunity to offer input to the organic regulatory process. Crystal Creek also manufactures high quality livestock nutritional supplements and health aids for organic livestock production, so we have a direct interest in which ingredients are allowed for use in organic livestock production.

The first category of comments are on ingredients that I support for continued inclusion on the National List and the second category of comments are on ingredients that I do not support for continued inclusion on the National List.

1) These are ingredients that I support for continued inclusion on the National List as currently stated:

Section 205.603 Synthetic substances allowed for use in organic livestock production.

a) As disinfectants, sanitizer, and medical treatments as applicable.
   1) Alcohols
   2) Aspirin
   3) Biologics – vaccines.
   4) Chlorhexidine
   5) Chlorine materials
   6) Electrolytes
   7) Glucose
   8) Glycerine
   9) Hydrogen peroxide
   10) Iodine
   11) Magnesium sulfate
   12) Oxytocin
   13) See disapprove comments
   14) Phosphoric acid

b) As topical treatment, external parasiticide or local anesthetic as applicable.
   1) Copper sulfate
   2) Iodine
   3) Lidocaine
   4) Lime
   5) Mineral Oil
   6) Procaine

c) As feed supplements – milk replacers without antibiotics, as emergency use only, no non-milk products or products from BST treated animals.

d) As feed additives.
2) Trace minerals
3) Vitamin

e) As synthetic inert ingredients as classified by the EPA, for use with non-synthetic substances or a synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.
1) EPA List 4

205.604 Non-synthetic substances prohibited for use in organic livestock production.

a) Strychnine

205.605 Nonagricultural (non-organic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

a) Non-synthetics allowed:
Acids
Agar – agar
Bentonite
Calcium carbonate
Carrageen
Colors
Dairy cultures
Diatomaceous earth
Enzymes
Flavors
Kaolin
Magnesium sulfate
Nitrogen
Oxygen
Prelate
Potassium chloride
Potassium iodide
Sodium bicarbonate
Sodium carbonate
Tartaric acid
Waxes
Yeast

b) Synthetics allowed:
Alginates
Ammonium bicarbonate
Ammonium carbonate
Ascorbic acid
Calcium citrate
Calcium hydroxide
Calcium phosphates
Carbon dioxide
Chlorine materials
Ethylene
Ferrous sulfate
Glycerides
Glycerin

Hydrogen peroxide
Lecithin – bleached
Magnesium carbonate
Magnesium chloride
Magnesium stearate
Nutrient vitamins and minerals
Foods
Ozone
Pectin
Phosphoric acid
Potassium hydroxide
Potassium iodide
Potassium phosphate
Silicon dioxide
Sodium citrate
Sodium hydroxide
Sodium phosphates
Sulfur dioxide
Tartaric acid
Tocopherols
Xanthan gum

205.606 Non-organically produced agricultural products allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food groups(s))."

a) Cornstarch
b) Gums
c) kelp
d) Lecithin
e) Pectin

2) The following are ingredients I disapprove of, reasons why and I recommend the ingredient be taken off of the National List.

205.603

13) Ivermectin - Should be take off of the National List due to its extremely toxic impact on soil and insect life over extended periods of time (over 6 months depending on species). One example of Ivermectin's negative impact on soil life is its ability to kill dung beetles, an insect critical to the incorporation of manure into soil, as well as to overall soil health and fertility. Based on research data proving Ivermectins negative and lingering environmental impact, it should be banned by the FDA much less be allowed for organic livestock production use. Effective, natural alternatives are available. References to negative environmental impacts can be found at;

Halley, B.A., Nessel, R.J. & Lu, A.Y.H. (1989) Environmental aspects of Ivermectin usage in livestock: general considerations.
Ivermectin and Abamectin (ed. W.C. Campbell), pp. 162 – 172. Springer – Verlag, New York.

Shoop WL, Mrozik H & Fisher MH (1995) Structure and activity of avarmectins and milbemycins in animal health. Veterinary
Parasitology 59: 139 – 156.

Strong, L. (1992). Avermectins: A review of their impact on insects of cattle dung.
Bulletin of Entomological Research, 82, 265 – 274.

Wardbaugh, K.G. & Rodriguez Menendez, H. 1988. The effects of the antiparasitic drug, Ivermectin, on the development and survival of the dung-breeding fly, *Urthelia comicina* (F) and the scarabaeine dung beetles, *Copris hispanus* L., *Bubas bubalus* (Oliver) and *Onitis belial* F. *Journal of Applied Entomolgy* 106: 381 – 389.

Floate, K.D. & Fox, A.S. (1999) Indirect effects of Ivermectin residues across trophic levels: Musca domestica (Diptera: Muscidae) and Musidifurax zaraptor (Hymenoptera: Pteromalidae). *Bulletin of Entomological Research* 89: 225 – 229.

Sincerely,

Dan Leiterman
President
Crystal Creek, A Division of Leiterman & Associates, Inc.